

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICA, N.V. and:
JANSSEN PHARMACEUTICA:
PRODUCTS,

Plaintiffs,

v.

APOTEX, INC.,

Defendant.

Hon. Dennis M. Cavanaugh

OPINION

Civil Action No. 06-cv-1020(DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon Plaintiffs Janssen Pharmaceutica, N.V. and Janssen Pharmaceutica Products, L.P.'s (Plaintiffs) motion to dismiss Defendant Apotex's Counterclaims III and IV regarding U.S. Patent Numbers 5,453,425 (the '425 patent) and 5,616,587 (the '587 patent) pursuant to Fed.R.Civ.P. 12(b)(1) and Defendant Apotex's motion for summary judgment seeking a declaratory judgment of non-infringement of the '425 patent and the '587 patent pursuant to Fed.R.Civ.P. 56 and L.Civ.R. 56.1. Pursuant to Rule 78 of the Federal Rules of Civil Procedure, no oral argument was heard. After carefully considering the submissions of the parties, and based on the following, this Court finds that Plaintiffs' motion to dismiss Defendant's Counterclaims III and IV is **granted**. As such, Defendant's motion for summary judgment is moot.

I. Background¹

Plaintiffs are the patent owners for various forms of risperidone. Specifically, Plaintiffs own “Risperidone Oral Formulation”, which is the ‘425 patent and “Aqueous Risperidone Formulations”, which is the ‘587 patent. Apotex is a manufacturer of various products, including the generic versions of Plaintiffs’ ‘425 and ‘587 patents, which it has researched and prepared for market. On or about March 3, 2006, Plaintiffs filed suit against Defendant, and other entities alleging patent infringement of U.S. Patent No. 4,804,663 (the ‘663 patent) for risperidone oral solution. On or about April 26, 2006, Defendant filed an answer and counterclaims, among other claims, seeking declaratory judgments of non-infringement of the ‘425 and ‘587 patents. Defendant agreed to be bound by a final, unappealable decision in the actions brought against the other entities regarding the ‘663 patent. On October 2, 2007, this Court entered a Judgment in favor of Plaintiffs and against Defendant with respect to the infringement claims of the ‘663 patent.

On June 28, 2006, Plaintiffs filed the present motion to dismiss Defendant’s Counterclaims III and IV, pertaining to patents ‘425 and ‘587. On January 30, 2007, Defendant filed the present motion for summary judgment for non-infringement of patents ‘425 and ‘587. On February 21, 2007, Judge Lifland Ordered a Stay of the summary judgment motion until this Court decided the motion to dismiss.

Plaintiffs move to dismiss Defendant’s Counterclaims III and IV pursuant to Fed.R.Civ.P. 12(b)(1) for lack of subject matter jurisdiction. Counterclaims III and IV seek declaratory judgment of non-infringement of patents ‘425 and ‘587 as Defendant alleges without Janssen’s approval, it would be unable to market the competing generic drugs.

¹The facts set forth in this Opinion are taken from the undisputed facts in each party’s moving papers.

Plaintiffs listed the ‘663, ‘425 and ‘587 patents in the United States Food and Drug Administration’s “Orange Book” in connection with Plaintiffs’ New Drug Application (NDA) for risperidone. The ‘663 patent covers the compound risperidone and the ‘425 and ‘587 patents cover aqueous solutions for risperidone and methods for preparing these solutions; thus, the ‘425 and ‘587 patents require more than simply risperidone.

Prior to September 16, 2005, Defendant submitted an abbreviated new drug application (ANDA) seeking to engage in the commercial manufacture of the generic version of risperidone oral solution. On September 16, 2005, Defendant sent Plaintiff a Paragraph IV Certification for the ‘425 and ‘587 patents. On January 26, 2006, Defendant amended its ANDA to assert a Paragraph IV Certification against the ‘663 patent. Plaintiff acted within 45 days of receiving the additional Paragraph IV Certification and brought a patent infringement suit regarding the ‘663 patent **only**. As shown above, this patent infringement is no longer in issue. In its Answer to Plaintiffs’ Complaint, Defendant counterclaims alleging non-infringement of the ‘425 and ‘587 patents and seeks declaratory judgment from this Court holding that Defendant has not infringed patents ‘425 or ‘587.

On December 8, 2006, Plaintiffs provided Defendant with a covenant not to sue for infringement of the ‘425 and ‘587 patents. This covenant not to sue protects Defendant and Defendant’s customers and distributors. While there may have been a case or controversy prior to Plaintiffs providing the covenant not to sue, no case or controversy exists regarding the ‘425 and ‘587 patents, as a result of the covenant not to sue. As such, this Court finds that Plaintiffs’ motion to dismiss Defendant’s Counterclaims III and IV, pertaining to the ‘425 and ‘587 patents is **granted** and Defendant’s motion for summary judgment is moot.

II. Standard of Review

MOTION TO DISMISS PURSUANT TO RULE 12(b)(1)

Upon a Rule 12(b)(1) motion addressing the existence of subject matter jurisdiction over a plaintiff's complaint, "no presumptive truthfulness attaches to a plaintiff's allegations." Martinez v. U.S. Post Office, 875 F. Supp. 1067, 1070 (D.N.J.1995) (citing Mortensen v. First Fed. Sav. and Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)). "Accordingly, unlike a Rule 12(b)(6) motion, consideration of a Rule 12(b)(1) jurisdiction-type motion need not be limited; conflicting written and oral evidence may be considered and a court may 'decide for itself the factual issues which determine jurisdiction.'" Id. (citing Williamson v. Tucker, 645 F.2d 404, 413 (5th Cir.) Cert. denied, 454 U.S. 897 (1981)). "When resolving a factual challenge, the court may consult materials outside the pleadings, and the burden of proving jurisdiction rests with the plaintiff." Med. Soc'y of N.J. v. Herr, 191 F. Supp. 2d 574, 578 (D.N.J. 2002) (citing Gould Elecs. Inc. v. U.S., 220 F.3d 169, 176, 178 (3d Cir. 2000)). However, "[w]here an attack on jurisdiction implicates the merits of plaintiff's [F]ederal cause of action, the district court's role in judging the facts may be more limited." Martinez, 875 F. Supp. at 1071 (citing Williamson, 645 F.2d at 413 n.6).

III. Discussion

After carefully reviewing the record and papers submitted by all parties, and based on the following, this Court finds that Plaintiffs' motion to dismiss Defendant's counterclaims III and IV is **granted** because there is no case or controversy surrounding the patents Defendant alleges are in issue.

At the time Plaintiffs filed their motion to dismiss, Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324 (Fed. Cir. 2005) was controlling law, which applied a two part test to determine whether there was a case or controversy. The two-part test required both an explicit threat or other action by the patentee which creates a reasonable apprehension of suit and present activity which would constitute infringement. Id. at 1332.

MedImmune, Inc. v. Genetech, Inc., 127 U.S. 764 (2007) is now controlling law to determine whether a justiciable declaratory judgment action exists. “Whether the facts alleged, under all the circumstances show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” Id. at 768. This Court, after considering the totality of the circumstances, finds that no substantial controversy exists and Plaintiffs’ motion to dismiss Defendant’s Counterclaims III and IV is granted.

Defendant asserts that Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals, 482 F.3d 1330 establishes that MedImmune is entirely applicable to the facts in this case, and thus mandates that subject matter jurisdiction exists in this declaratory judgment action. However, the present action is distinguished from Novartis as Plaintiffs point out, there was no covenant not to sue in Novartis. Novartis at 1332.

In reaching its decision in Novartis, the Circuit reviewed the legislative history of the declaratory judgment provision of the Hatch-Waxman Act² and held that a covenant not to sue

²The Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §§355, 360cc and 35 U.S.C. §§156, 271, 282 is commonly known as The Hatch-Waxman Act. The Act requires an innovator pharmaceutical company that seeks to manufacture a new brand drug to file a New Drug Application with the Federal Food and Drug Administration.

usurps the opportunity to bring an action for declaratory judgment.

We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.

Novartis at 1338. In this case, a covenant not to sue was given to Defendant on December 8, 2006. Further, in Merck & Co. v. Apotex, (06-230), The United States District Court for the District of Delaware issued an Order on April 10, 2007 granting Merck's motion to dismiss for lack of subject matter jurisdiction because of Merck's covenant not to sue.

The same situation arises here. Plaintiffs gave Defendant a covenant not to sue, and therefore Plaintiffs' motion to dismiss regarding the patents in the covenant not to sue must be granted.

IV. Conclusion

Based on the foregoing facts and law, it is clear that there is no case or controversy regarding patents '425 and '587, and as such, this Court does not have subject matter jurisdiction and must dismiss Defendant's counterclaims III and IV. Plaintiffs' motion to dismiss Defendant's Counterclaims III and IV is granted and Defendant's motion for summary judgment seeking declaratory relief regarding patents '425 and '587 is moot. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: October 11, 2007
Orig: Clerk's Office
cc: Counsel of Record
The Honorable Mark Falk, U.S.M.J.
File